MDS-UPDRS Training

Slides to be inserted
BREAK

Presentations will resume at 10:45 am
Safety Reporting and Monitoring

Presented by:
Emily Flagg
Project Manager - CTCC
Overview

- Adverse events (AEs)
- Serious adverse events (SAEs)
- Incidents
- Notifications
- Clinical Study Oversight Committee (CSOC)
Adverse Events

- An AE is any untoward medical occurrence in a subject enrolled in a study after informed consent has been obtained.

- Will be captured once a DAT scan or lumbar puncture is completed through the time of the 7 day follow up phone call.
Examples of AEs include:

- Any reaction from injection of imaging tracer or lumbar puncture (e.g., pain, headache, dizziness)
- Injury or accident during 7-day reporting period following DAT scan or LP
- Development of intercurrent illness during 7-day reporting period following DAT scan or LP
Adverse Events

- Adverse events are determined by subject report as well as by clinical judgment of the investigator
- Assessed on day of visit following a DAT scan and/or lumbar puncture
- Assessed by phone 7 (±3) days following DAT or LP procedure
Recording Adverse Events

- All AEs captured on the Adverse Event Log data form

- Data form includes:
  - Description of AE
  - Severity
  - Relationship to the study
  - Seriousness (AE vs. SAE)
AE Severity

- Based on the Investigator's clinical judgment and graded as follows:
  - **Mild** – usually transient in nature and generally not interfering with normal activities
  - **Moderate** – sufficiently discomforting to interfere with normal activities
  - **Severe** – prevents normal activities
AE Relationship to Study

• As determined by the Investigator

• Indicating whether there is a reasonable possibility of a relationship between the AE and a study procedure or the DaTSCAN™
  • Possible
  • Probable
  • Definite
  • Unlikely

• No reasonable possibility of such a relationship
  • Unrelated
Record all adverse events that occur during the study period (defined as from signing consent to conclusion of study participation). Record disease entity as AE only if it worsens beyond what investigator expects is within normal range of fluctuation for this subject. Elicit adverse event data by asking an open-ended question, e.g., “What unusual symptoms or medical problems have you experienced since the last visit?” Record any new or change in ongoing sign or symptom as well as any event that has resolved since last evaluation. Enter each change in “severity” on new line. Date: Please specify if the Start and Stop dates are ACTUAL or ESTIMATED. If the exact date is unknown, please enter your best reasonable estimate of the date and specify which part(s) are estimated. If EVENT IS A SERIOUS ADVERSE EVENT, please refer to the Operations Manual for reporting guidance.

<table>
<thead>
<tr>
<th>AE # (e.g., 1, 2, etc.)</th>
<th>Adverse Event (Record diagnosis if known)</th>
<th>START DATE (MM/DD/YYYY)</th>
<th>STOP DATE (MM/DD/YYYY)</th>
<th>Severity</th>
<th>SAE</th>
<th>Relationship to Study</th>
<th>Complete when resolved or at Final Visit</th>
<th>Primary Outcome</th>
<th>AE Status at Final Visit</th>
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</tbody>
</table>

INVESTIGATOR’S SIGNATURE

DATE

STAFF CODE

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AE Follow Up

- All AEs should be evaluated at each subsequent visit and until the event or its sequelae resolve or stabilize at an acceptable level
  - Enter follow-up information on the AE Log

- Any ongoing AE at the final 7 day reporting telephone call should be followed until resolution or stabilization
Serious Adverse Events

- An SAE is any AE that results in any of the following outcomes:
  - Life-threatening adverse event
  - Hospitalization or prolongation of existing hospitalization
  - A persistent or significant disability/incapacity
  - A congenital anomaly/birth defect
  - Death
Reporting Serious Adverse Events

- SAEs must be reported to the CTCC project manager as soon as possible and **within 24 hours** of awareness.
- Complete the MedWatch form and email to the CTCC project manager.
- Updates/modifications to initial report must also be made within 24 hours of site awareness.
- Sites to notify the IRB within 10 days of awareness of event.
Clinical Study Oversight Committee

• Assess safety by review of:
  • AEs and SAEs
  • Premature Withdrawals
  • Protocol Violations
• Meet twice a year
• Prepare written reports to Steering Committee of recommendations for the study
Questions?
Good Clinical Practices and Study Monitoring

Emily Flagg, Project Manager - CTCC
• Good Clinical Practices (GCP)
  • Standards for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of trial subjects are protected

• Compliance (in clinical trials):
  • Adherence to all the trial-related requirements, GCP requirements, and the applicable regulatory requirements
The PPMI study will adhere to ICH and FDA regulations

- Investigator Responsibilities
  - International Conference on Harmonization (ICH) Guidelines (E6 – Good Clinical Practice)
  - 21CFR312 Subpart D
Importance of Compliance

- Protection of human subjects
- Legal and ethical requirements
- Protect the integrity of the trial outcome
- Avoid any compromise of professional integrity
Formula for Compliance Success

- Regulations and responsibilities are defined
  - Learn/understand them
  - Refer to them often
  - Respect them
- Train on GCP / Practice GCP
- Follow the protocol
- Keep accurate records
  - Remember, if it’s not documented, it didn’t happen!
How to Handle Non-Compliance

- Communicate
- Institute and document corrective actions
- Retrain as necessary
- Establish an ongoing re-assessment
- Carefully review data queries requested
- Promptly execute follow-up for actions identified during monitoring visits
Investigator Qualifications & Agreements

- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the study.
- Be thoroughly familiar with the appropriate use of the (investigational) product (DaTSCAN™) as described in the protocol and current IB.
- Be aware of and comply with GCP/ICH and other applicable regulatory requirements.
- Permit monitoring.
- Maintain a list of qualified persons to whom significant trial-related duties are delegated.
Investigator Responsibilities

- Maintain adequate records of receipt and use of the DaTSCAN™
- Prepare and maintain adequate and accurate source information
- Complete all required reports
- Oversee the conduct of the study at your site
Informed Consent is **not** a form... it’s a process

- An exchange of essential information about the research study
- Allows the participant to ask questions & have them answered
- Is evidenced by the signing of the informed consent document and giving a copy to the subject
- Is documented in source documents
- Continues at each interaction and by providing the participant new information as applicable
Study Monitoring
Monitoring Overview

- Clinical Study Oversight Committee (CSOC)
- Steering Committee (SC)
- Site Monitoring Team
Site Monitoring

- Monitors will conduct an on-site monitoring visit after first 2 subjects are enrolled.
- Subsequent visits will be annually.
- Monitoring responsibilities for the study include:
  - reviewing regulatory documentation filed at site,
  - ensuring protocol compliance on site,
  - comparing source-documents to entries in the eDE system
  - reviewing records for receipt and use of DaTSCAN™
Coordination of Visits/Contacts

- Monitors are responsible for arranging site visits with Site Coordinator and Investigator
  - Based on enrollment activities

- Site visit communications will be documented through the following:
  - Pre-visit letter to site with list of activities planned (e.g., records to review)
  - Interaction during the visit with an update on progress and identification of any action items necessary
  - Follow-up letter with documentation of findings, issues and concerns
At each Periodic Monitoring Visit, the monitor will:

- Review screening/enrollment procedures
- Review Informed Consents
- Complete source document verification
- Review Regulatory Binder documentation, including study-related training records for staff involved
- Review accountability and management of the DaTSCAN™
Questions?
Sample Access

Slides to be inserted
PPMI Website Audience

- PPMI Website will provide resources for PPMI Participants:
  - Acquisition Sites
  - Funded Researchers
  - Non-Funded Researchers
<table>
<thead>
<tr>
<th>Main Pages</th>
<th>Sub Pages</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home</td>
<td></td>
<td>Main home page</td>
</tr>
<tr>
<td>About Parkinson’s</td>
<td></td>
<td>General information about Parkinson’s Disease</td>
</tr>
<tr>
<td>Our Research</td>
<td></td>
<td>Main research page and study information</td>
</tr>
<tr>
<td>About PPMI</td>
<td></td>
<td>Information about PPMI</td>
</tr>
<tr>
<td>Our Team</td>
<td></td>
<td>People involved in PPMI</td>
</tr>
<tr>
<td>Research Groups</td>
<td></td>
<td>Sub-groups and their research</td>
</tr>
<tr>
<td>Research Guidelines</td>
<td></td>
<td>Guideline documents for publications, authorship, committees, data use, etc</td>
</tr>
<tr>
<td>Publications</td>
<td></td>
<td>Publications by PPMI researchers</td>
</tr>
<tr>
<td>Presentations</td>
<td></td>
<td>Powerpoint presentation archive on Parkinson’s Disease topics</td>
</tr>
<tr>
<td>Funding</td>
<td></td>
<td>Information about PPMI funding</td>
</tr>
<tr>
<td>Data</td>
<td></td>
<td>Main data page</td>
</tr>
</tbody>
</table>

Cont’d on next page
<table>
<thead>
<tr>
<th>Main Pages</th>
<th>Sub Pages</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data</td>
<td></td>
<td>Main data page</td>
</tr>
<tr>
<td>Data Archive*</td>
<td></td>
<td>Information about types of data and link to the data archive section. *This will link to the repository which is not represented in this hierarchy.</td>
</tr>
<tr>
<td>Data FAQ</td>
<td></td>
<td>Frequently asked questions about the data archive</td>
</tr>
<tr>
<td>Data Use</td>
<td></td>
<td>Data use agreement for current or potential users</td>
</tr>
<tr>
<td>Acquisitions Sites</td>
<td></td>
<td>Information about where the data is collected</td>
</tr>
<tr>
<td>Patient Security</td>
<td></td>
<td>Information on patient data rights and HIPAA rules</td>
</tr>
<tr>
<td>Data Contact</td>
<td></td>
<td>A redundant link to the contact page which serves to funnel people into the right place to ask questions about the data</td>
</tr>
<tr>
<td>News</td>
<td></td>
<td>General news page</td>
</tr>
<tr>
<td>Blog</td>
<td></td>
<td>Blog page or Twitter page link to announce PPMI news</td>
</tr>
<tr>
<td>Media</td>
<td></td>
<td>Any media coverage of the PPMI work, ie online articles about PPMI, tv coverage, journal articles, etc</td>
</tr>
<tr>
<td>Contact</td>
<td></td>
<td>Contact page for interested parties, website contact info and data archive contact info.</td>
</tr>
</tbody>
</table>
Admin Features

- Content Management System
  - Document Management
  - Multi-level Roles
  - Revision Control
  - Search Engine Optimization
  - Easy editing of pages and news items
Admin Features

• Content Management System

• Document Management: documents are archived by date and user

• Multi-level Roles: any user can be assigned to edit and add content to the website, such as news for a specific core

• Revision Control: revert to previous page edits

• Search Engine Optimization: techniques employed for getting high page rankings and reaching a larger audience

• Easy editing of pages and news items: Microsoft Word-like interface for quickly updating content and keeping the site “fresh”
Admin Page Editing

Module Definitions

The module definitions for some popular packages have been provided here for your convenience so that you will not have to create the definitions yourself. In order run these modules locally, change the executable path within the module definition to point to the appropriate location.

All Packages

All Module Definitions

Individual Packages

Custom Fields

Discussion

Page Author

Page Revisions

9 February, 2009 @ 12:08 by zlui
23 September, 2008 @ 15:58 by zlui
23 September, 2008 @ 15:57 [Autosave] by kaliprando
25 August, 2008 @ 13:54 by cmena

Publish

Save Draft  Preview

Status: Draft Edit
Visibility: Public Edit
Published on Aug 19, 2008 @ 15:45 Edit

Delete

Publish

Attributes

Parent

Main Page (no parent)

You can arrange your pages in hierarchies, for example you could have an "About" page that has "Life Story" and "My Dog" pages under it. There are no limits to how deeply nested you can make pages.

Template

Default Template

Some themes have custom templates you can use for certain pages that might have additional features or custom layouts. If so, you'll see them above.

Order

1

Pages are usually ordered alphabetically, but you can put a number above to change the order pages appear in. (We know this is a little
## Admin User Roles

### Users

<table>
<thead>
<tr>
<th>Username</th>
<th>Name</th>
<th>E-mail</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>admin</td>
<td>Amanda Hammond</td>
<td></td>
<td>Administrator</td>
</tr>
<tr>
<td>ahammond</td>
<td></td>
<td></td>
<td>Administrator</td>
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<tr>
<td>cmena</td>
<td>Carlos Mena</td>
<td></td>
<td>Editor</td>
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<tr>
<td>dhasan</td>
<td>David Hasson</td>
<td></td>
<td>Administrator</td>
</tr>
<tr>
<td>kalinrando</td>
<td>Katie Aliprado</td>
<td></td>
<td>Editor</td>
</tr>
<tr>
<td>klozev</td>
<td>Kamen Lozev</td>
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<td>Editor</td>
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<tr>
<td>ppetrosyan</td>
<td>Petros Petrosyans</td>
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<td>Editor</td>
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<tr>
<td>rdelacruz</td>
<td>Robert De La Cruz</td>
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<td>Administrator</td>
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<tr>
<td>vgreer</td>
<td>Vaughan Greer</td>
<td></td>
<td>Editor</td>
</tr>
<tr>
<td>zliu</td>
<td>Zhizhong Liu</td>
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<td>Editor</td>
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</table>
User Features

- Data access
- Powerful search capabilities
- Protocols
- Research guidelines
- Data sharing policies and procedures
- Technical manuals
- Authorship list and citation information
- General news updates
- Specific core or data news
- Subscriptions
- FAQs
- Contact information
- Meeting PowerPoints and minutes
## User Features

**in detail...**

<table>
<thead>
<tr>
<th>Visitors can access</th>
<th>Needs approval to view/submit</th>
<th>Can be edited by user if given role</th>
</tr>
</thead>
</table>

- **Data access**
- **Powerful search capabilities**
- **Protocols**
- **Research guidelines**
- **Data sharing policies & procedures**
- **Technical manuals**
- **Authorship list and citation information**
- **General news updates**
- **Specific core or data news**
- **Subscriptions**
- **FAQs**
- **Contact information**
- **Meeting PowerPoints and minutes**
Presentations will resume at 1:00 pm
Publication Policy

Slides to be inserted
FINDING THE CURE FOR PARKINSON'S TAKES AN ORGANIZATION WITH EXTRAORDINARY VISION.
The best minds around the world and an innovative approach to research are helping us put a cure in sight.

Michael J. Fox with MJFF CEO Katie Hood (left) and Co-Founder Debi Brooks
PPMI
Communications & Reports

Emily Flagg, Project Manager - CTCC
Central Lab
Coordination Center (CTCC)
Michael J. Fox Foundation (MJFF)
Imaging Core (IND)
Imaging Core (IND)
Bioinformatics Core (LONI)
Bioinformatics Core (LONI)

Central Lab
Coordination Center (CTCC)
Michael J. Fox Foundation (MJFF)
Imaging Core (IND)
Bioinformatics Core (LONI)

Steering Committee
Site Monitors
CSOC
Statistics Core
Bioanalytics Core
Biorepository (Coriell)
Genetics Core
Study Contacts
CTCC Team

- Emily Flagg
  Lead Project Manager

Phone: (585) 275-8869
Fax: (585) 461-3554
Email: emily.flag@ctcc.rochester.edu

- Protocol Questions
  - Eligibility, General questions
  - Reportable Events (Incidents, including SAEs)
  - Regulatory Documents and Staff Changes
CTCC Team

- Alice Rudolph
  
  Project Manager
  Phone: (585) 275-0556
  Fax: (585) 461-3554
  Email: alice.rudolph@ctcc.rochester.edu

- Back up to Lead PM
Study Contacts

CTCC Team

- Sue Bennett
  
  Information Analyst
  Phone: (585) 273-4234
  Fax: (585) 461-4594
  Email: susan.bennett@ctcc.rochester.edu

  - Data Management
    - eCRF Issues
    - Query Management
    - Missing Forms Reports
    - Study Closeout
Site Personnel

- One Primary Investigator
  - Sub-investigators accepted as approved by sponsor and study team
  - Subjects screened/enrolled by a sub-I should be followed by same individual throughout for consistency of assessments and evaluations

- One Primary Coordinator
  - Co-coordinators accepted as approved by sponsor and study team

- Investigator is responsible for seeing all subjects at all visits and conducting Investigator required assessments

- Any change in Investigator must be preapproved by the PPMI Steering Committee
Site Personnel

- Report staff changes to the CTCC as soon as possible (complete the new/change staff form)

- Update Log of Investigators, Study Staff and Staff Related Duties (fax copy to CTCC)

- Update 1572 (if applicable)
Confirmation to Enroll

- Requirements include:
  - IRB approval
  - Subcontract in place
  - Regulatory documents completed
  - PI and Coordinator protocol training completed
  - eDE training (if not previously done)

- Approval memo to begin recruitment and enrollment received from the CTCC

- Additional study team members notified
Reports
Enrollment Confirmation

- Enrollment Verification Report Generated
  - Report appears on RANDOM page once page is completed after eligibility confirmed and subject completes Baseline visit
- Visit Window Schedule with Target Visit Dates
- Check for accuracy; notify CTCC Project Manager if any corrections are required
- Print and file in study binder
Activity Report

- Site included on report once actively enrolling
- Includes summary study information by site about total enrollment, withdrawals, SAEs
Incident Report

- Generated from reportable events, including:
  - Serious adverse event
  - Start of PD medication (PD subjects only)
  - Subject withdrawal from participation
- Summary of the event as reported to CTCC
- Sites to review and verify information upon receipt
- Print copy for study file
The following events are considered reportable events (incidents) and must be reported to the CTCC project manager as soon as possible and within 24 hours of site awareness:

- Initiation of any PD medication
- Change of diagnosis (PD and HC subjects)
- Participation in any other clinical trial or study
- Premature withdrawal (e.g., withdrawal of consent)
- Serious adverse event (SAE)
- Pregnancy
- Death
Incident Report

- Summary of the event as reported to CTCC
- Sites to review and verify information upon receipt
- Print copy for study file
Notifications

• Purpose: to report noteworthy and relevant clinical or data management information that might influence the interpretation of the study data

• May be a general site issue as well as subject specific

• Notifications should be communicated by telephone or email to the CTCC within 3 days of site awareness
Notifications

- Examples of issues requiring notification:
  - Protocol violation
  - Blood sample not processed correctly
- Include with the report to CTCC:
  - Site number
  - Staff code of Investigator or Coordinator reporting
  - Subject ID number
  - Date of event or observation
Notification Report

- Generated as a summary of the event as reported to the CTCC
- Sites to review and verify information upon receipt
- Print copy for study file
General Communications

- Periodic phone calls and teleconferences
- Additional protocol training as needed
- General email communications
- Questions?
  - Call Emily Flagg
  (585) 275-8869
eClinical Training
Introduction

Joe Weber
University of Rochester
Clinical Trials Coordination Center
OmniComm eClinical

- Web-based trial management system
- Accessible with a Windows PC and Internet Explorer
  - Not accessible with a Macintosh
  - Not accessible with other browsers such as FireFox, Chrome or Safari
System Availability

- System available 24x7
  - Maintenance window of 8am-Noon ET on Sundays
  - Daily restart at 6am ET
ePortal

- Main screen for the application
- Access to study documents
  - Protocol
  - Operations Manual
  - Source Document Worksheets
Electronic Data Capture

- Allows you to:
  - Create patients
  - Enter clinical data
  - Apply electronic signatures
  - Address data queries
<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Initials</th>
<th>Baseline Visit Date</th>
<th>Country</th>
<th>Entry Status</th>
<th>Batch Status</th>
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<td>Description</td>
<td>Visit Date</td>
<td>Entry Status</td>
<td>Event Order</td>
<td>Batch Status</td>
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<tr>
<td>CONSENT</td>
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<tr>
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<td></td>
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<td>5</td>
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</tr>
<tr>
<td>T01</td>
<td>Telephone 1 (Week 1)</td>
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<td>6</td>
<td>$</td>
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<tr>
<td>V01</td>
<td>Visit 1 (Month 1)</td>
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<td>7</td>
<td>$</td>
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<tr>
<td>V02</td>
<td>Visit 2 (Month 2)</td>
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<td>Unscheduled</td>
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</tr>
</tbody>
</table>
Complete one form for each subject who is potentially eligible to participate in the study.

A. Check box if subject has signed consent

B. Date informed consent was signed

C. Indicate the type of subject: 1 = Parkinson disease, 2 = Healthy control

1. Date of birth

2. Gender (0 = Female of child bearing potential, 1 = Female of non-child bearing potential, 2 = Male)

Women who are surgically sterile (hysterectomy or tubal ligation) or post-menopausal (last menstruation was 1 year or more prior to Screening Visit) are considered to be of non-childbearing potential.
### AE (Adverse Event Log)

**LOGHEAD**

- **Subject Initials:** JOE
- **Investigator's staff code:** 1324

### AE (Adverse Event)

<table>
<thead>
<tr>
<th>AE#</th>
<th>Adverse Event (Record diagnosis if known)</th>
<th>Start Date MMDDYYYY</th>
<th>Start Date Estimated? (ACT,DAY MD,MON)</th>
<th>Stop Date MMDDYYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HEADACHE</td>
<td>07012009</td>
<td>ACT</td>
<td></td>
</tr>
</tbody>
</table>
Training

- Training will be provided via webinar

- After successful completion of certification exam, you will be given a username and password to access the system
Your user account will be the same for any other studies you do with the CTCC

If you have received training previously and already have an account, you do not need to attend a training session again
Support

- System support website available at: http://support.ctcc.rochester.edu/
  - User Guide reference materials
  - Frequently Asked Questions
  - Training Videos will be posted soon

- Telephone help desk support available from 8:30am – 9:00pm ET Monday-Friday. (585) 275-3893
<table>
<thead>
<tr>
<th>Activity</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site selection completed</td>
<td>January 2010</td>
</tr>
<tr>
<td>Study protocol finalized and submitted to central IRB</td>
<td>February 2010</td>
</tr>
<tr>
<td>Contracting for sites and cores</td>
<td>Feb-March 2010</td>
</tr>
<tr>
<td>PPMI Investigators Meeting</td>
<td>March 18-19 2010</td>
</tr>
<tr>
<td>Site training and set-up</td>
<td>March/April 2010</td>
</tr>
<tr>
<td>First subjects enrolled</td>
<td>April/May 2010</td>
</tr>
<tr>
<td>Subject recruitment/media program launched</td>
<td>April-May 2010</td>
</tr>
</tbody>
</table>
THANK YOU!

We appreciate you taking the time to join us at this meeting, and look forward to beginning this very exciting study!